

RECEIVED

MAY 08 2002

TECH CENTER 1600/2900



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: ZACHRIE

Serial No.: 09/976,249

Group Art Unit: 1616

Filed: October 15, 2001

Examiner: Unassigned

For: DIOXOLANE ANALOGS FOR IMPROVED INTER-CELLULAR DELIVERY

DHS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Assistant Commissioner for Patents
Washington, D. C. 20231

Sir:

CITED MATERIALS

Applicant(s) hereby disclose the information listed in the attached form PTO-1449.

- Copies of materials listed but not attached were cited in parent application Serial No. ____; see 37 C.F.R. § 1.98(d).
- Copies of materials listed but not attached were cited in an International Search Report dated ____; receipt of the International Search Report and copies of references was confirmed by the PCT International Division of the U.S. PTO in the Notice of Acceptance mailed ____.

ADDITIONAL INFORMATION

[NONE?]

LANGUAGE

- All listed materials are in the English language; see 37 C.F.R. § 1.98.
- Non-English language references:
- The reference(s): _____ in the English-language is (are) indicated by commercial data bases to correspond to the reference(s): _____, respectively.
- (An) English-language translation(s) of the references: _____ is (are) provided.
- A commercial English-language abstract of reference(s) _____ is (are) provided.
- An English-language search report or an equivalent paper from a foreign patent office translated into English in pertinent part in connection with a counterpart foreign application, is provided indicating the relevance of the cited reference(s).



FEES

- No fee is required for this Information Disclosure Statement because:
- This Information Disclosure Statement is being filed within three months of the filing date of a national application (other than a CPA) under § 1.53(d) or within 3 months of the date of entry of the national stage under § 1.491 in an international application;
- This Information Disclosure Statement is being filed before the mailing of a first action on the merits;
- This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that closes prosecution in the application, and is accompanied by a certification below.
- This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(i).
- A fee is required for this Information Disclosure Statement:
- This Information Disclosure Statement is being filed after a first action on the merits but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311 or an action that closes prosecution, and is accompanied by the fee set forth in § 1.17(p).
- This Information Disclosure Statement is being filed after the mailing date of a final rejection or a notice of allowance under § 1.311 or an action that closes prosecution, but before the payment of the issue fee, and is accompanied by the fee set forth in § 1.17(p) and a certification below.

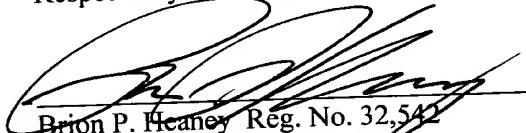
CERTIFICATION

- Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned, having made reasonable inquiry, no such item was known to any individual designated in 37 CFR § 1.56(c), more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

If a fee is due, attached is a check in the amount of \$ _____. However, the Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



Brion P. Heaney Reg. No. 32,542
Attorney/Agent for Applicants

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Blvd. Suite 1400
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: PHARMA-123

Date: May 7, 2002
BPH/casK:\PHARMA\123\IDS.doc

Please type a plus sign (+) inside this box → +

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

of 3

Complete if Known

Application Number	PHARMA-123
Filing Date	October 15, 2001
First Named Inventor	BOULOUS ZACHARIE et al.
Group Art Unit	1616
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-123

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	M.P.. DI MARCO ET AL., <u>Journal of Chromatography</u> , 645, (1993) 107-114 Elsevier Science Publishers, B.V. Amsterdam, "High-performance liquid chromatographic determination of the isomeric purity of a series of dioxolane nucleoside analogues".	
	2	HAOLUN JIN ET AL. <u>Tetrahedron Asymmetry</u> Vol. 4, No. 2 pp 211-214, 1993, "Unexpected Effects of Lewis Acids in the Synthesis of Optically Pure 2'-Deoxy-3'-oxacytidine Nucleoside Analogues"	
	3	COLLEEN A. EVANS ET AL. <u>Tetrahedron: Asymmetry</u> Vol. 4, No. 11, pp. 2319-2322, 1993 "Divergent Asymmetric Syntheses of Dioxolane Nucleoside Analogues"	
	4	ARSHAD SIDDIQUI ET AL., <u>Bioorganic & Medicinal Chemistry</u> , Vol. 3, No. 8, pp. 1543-1546, 1993, "Antiviral Optically Pure Dioxolane Purine Nucleosides Analogues"	
	5	BERNARD R. BELLEAU ET AL., <u>Tetrahedron Letters</u> , Vol. 33, No. 46, pp. 6949-6952, 1992 "Oxidative Degradation of L-Ascorbic Acid Acetals to 2',3'-Dideoxy-3'-Oxaribofuranosides. Synthesis of Enantiomerically Pure 2',3'-Dideoxy-3'-Oxacytidine Stereoisomers as Potential Antiviral Agents"	
	6	HEA O. KIM ET AL., <u>Tetrahedron Letters</u> , Vol. 33, No. 46, pp. 6899-6902, 1992, "Potent Anti-HIV and Anti-HBV Activities (-)-L-β-Dioxolane-C and (+)-L-β-Dioxolane-T and Their Asymmetric Syntheses"	
	7	JOHN R. MACKEY ET AL., <u>Cancer Research</u> , 58, 4349-4357, October 1, 1998 "Functional Nucleoside Transporters Are Required for Gemcitabine Influx and Manifestation of Toxicity in Cancer Cell Lines"	
	8	KRISTIE L. GROVE AND UUNG-CHI CHENG, <u>Cancer Research</u> , 56, 4187-4191, September 15, 1996, "Uptake and Metabolism of the New Anticancer Compound β-L-(\cup -Dioxolane-Cytidine in Human Prostate Carcinoma DU-145 Cells"	
	9	US Patent 5,041,449, Belleau et al.	
	10	US Patent 5,817,667, Chu et al.	
	11	WENDY P. GATI AND ALAN R. P. PATERSON, <u>The American Society for Pharmacology and Experimental Therapeutics, Molecular Pharmacology</u> , 36:134-144, "Interaction of (3H) Dilazep at Nucleoside Transporter-Associated Binding Sites on S49 Mouse Lymphoma Cells"	

RECEIVED
FACILITY CENTER 1600/2900
MAY 08 2002

RECEIVED

Please type a plus sign (+) inside this box → +

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

3

Complete if Known

Application Number	PHARMA-123
Filing Date	October 15, 2001
First Named Inventor	BOULOUS ZACHARIE et al.
Group Art Unit	1616
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-123

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	12	Proc. Amer. Assoc. Cancer Res. 37:405 (1996), "Use of SAENTA-fluorescein in a flow cytometric assay of cellular es nucleoside transporter site abundance, a correlate of chemosensitivity to cytarabine in acute myeloid leukemia cells"	
	13	KATHRYN A. GRAHAM ET AL., <u>Nucleosides, Nucleotides & Nucleic Acids</u> , (19(1&2), 415-434 (2000), "Differential Transport of Cytosine-Containing Nucleosides by Recombinant Human Concentrative Nucleoside Transporter Protein hCNT1."	
	14	ERIC R. HARLEY ET AL., <u>Cancer Research</u> , 42, 1289-1295, April 1982, "Initial Rate Kinetics of the Transport of Adenosine and 4-Amino-7-(β -D-ribofuranosyl) pyrrolo(2,3-d) pyrimidine (Tubercidin) in Cultured Cells"	
	15	CHARLES R. CRAWFORD ET AL., <u>Biochimica et Biophysica Acta</u> . 1024 (1990) 289-297, "Identification and reconstitution of the nucleoside transporter of CEM human leukemia cells"	
	16	MABEL W. L. RITZEL ET AL., <u>Molecular Membrane Biology</u> , 1998, 15, 203-211, "Molecular cloning, functional expression and chromosomal localization of a cDNA encoding a human Na ⁺ /nucleoside cotransporter (hCNT2) selective for purine nucleosides and uridine"	
	17	MABEL W. L. RITZEL ET AL., <u>American Physiological Society</u> 0363-6143/97, "Molecular cloning and functional expression of cDNAs encoding a human Na ⁺ -nucleoside cotransporter (hCNT1)"	
	18	BUDDY ULLMAN, <u>J. Physiol (Lord)</u> 1989 (Sept). 601:416-421, "Dideoxycytidine Metabolism in Wild Type and Mutant Cem Cells Deficient in Nucleoside Transport or Deoxycytidine Kinase"	
	19	HARALABIA BOLETI ET AL., <u>Neuropharmacology</u> , Vol. 36, No. 9, pp. 1167-1179, 1997, "Molecular Identification of the Equilibrative NBMPR-sensitive (es) Nucleoside Transporter and Demonstration of an Equilibrative NBMPR-insensitive (ei) Transport Activity in Human Erythroleukemia (K562) Cells"	
	20	CHRISTINE E. BOUMAH, DOUGLAS L. HOGUE AND CAROL E. CASS, <u>BioChem J.</u> (1992, 288, 987-996, "Expression of high levels of nitrobenzylthioinosine sensitive nucleoside transport in cultured human choriocarcinoma (BeWo) cells"	

RECEIVED
TECH CENTER 1600/2900
MAY 08 2002

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3 of 3

Complete if Known

Application Number	PHARMA-123
Filing Date	October 15, 2001
First Named Inventor	BOULOUS ZACHARIE et al.
Group Art Unit	1616
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-123

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	21	XIAO FANG ET AL., <u>Biochem J. (1996) 317, 457-465</u> , "Functional characterization of a recombinant sodium-dependent nucleoside transporter with selectivity of pyrimidine nucleosides (cNT1) by transient expression in cultured mammalian cells"	
	22	WENDY P. GATI ET AL., <u>Biochem J. (1989) 263, 957-960</u> , "Enantiomeric selectivity of adenosine transport systems in mouse erythrocytes and L1210 cells"	
	23	DOUGLAS L. HOGUE ET AL, <u>Biochem. Cell. Biol. Vol. 68, 1990</u> , "Effects of inhibitoion of N-linked glycosylation by tunicamycin on nucleoside transport polypeptides of L1210 leukemia cells"	
	24	JOHN R. MACKEY ET AL., <u>Cancer Research 58, 4349-4357, October 1, 1998</u> , "Functional Nucleoside Transporters Are Required for Gemcitabine Influx and Manifestation of Toxicity in Cancer Cell Lines"	
	25	ALAN R. P. PATERSON ET AL., <u>1991 Elsevier Science Publishers BV, Chapter 13</u> , "Plasma Membrane Transport of Nucleosides, Nucleobases and Nucleotides: an overview"	
	26	BUDDY ULLMAN ET AL, <u>The Journal of biological Chemistry, Vol. 263, No. 25, Issue of September 5, pp. 12391-12396, 1988</u> , "Genetic Analysis of 2',3'-Dideoxycytidine Incorporation into Cultured Human T Lymphoblasts"	
	27	JOANNE M. UPSTON, ANNETTE M. GERO, <u>Biochimica et Biophysica Acta 1236 (1995) 249-258</u> , "Parasite-induced permeation of nucleosides in <i>Plasmodium falciparum</i> , malaria"	
	28	MACKY ET AL., <u>Drug Resistance Updates</u> , (1998) I, 310-324, "Nucleoside transport and its significance for anticancer drug resistance"	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED
OCT 08 2002
U.S. PATENT AND TRADEMARK OFFICE
1600 29th Street, NW
Washington, DC 20231